

## **REMARKS**

### **1. Status of the Claims**

Claims 25-28 have been added to the application and are supported by original claims 10-13 and the specification at page 6, lines 2-13. Claims 25-28 correspond to Group I. Therefore, claims 10-18 and 20-28 are presented for substantive examination.

### **2. Elections/Restrictions**

The Examiner has maintained the Restriction Requirement between Group I and II, essentially urging that the originally presented product claim 10 did not define the dedifferentiated plant cells as being “halophile plant cells” and the presence of this limitation in amended claim 10 does not obviate the Restriction Requirement. Without admitting that original claim 10 was not patentable over the prior art, amended claim 10 (as further discussed below) is patentable over the prior art and, therefore, does indeed define a technical feature which distinguishes over the prior art. In this circumstance, the Examiner should withdraw the Restriction Requirement as lacking sufficient basis. There is no basis for the Examiner to maintain the Restriction Requirement without even considering Applicants’ amended claims.

### **3. Oath/Declaration**

The Application Data Sheet submitted with the application on June 28, 2006 properly identifies the priority information for this application. In addition, the specification has been amended to properly identify the priority applications. A corrected/supplemental Declaration and Power of Attorney will be submitted as soon as it is received from the Applicant.

#### **4. Specification**

The Examiner has objected to some informalities in the specification. The specification has been amended to correct any typographical errors and/or other informalities. Therefore, reconsideration and withdrawal of the objection are requested.

#### **5. Drawings**

Submitted herewith are substitute drawings which include properly translated legends and other text. Approval of these drawings and withdrawal of the objection are requested.

#### **6. Claim Objections**

The dependency of claim 12 has been corrected, so reconsideration and withdrawal of the objection are requested.

#### **7. Claim Rejections – 35 U.S.C. § 112**

##### 7.1. Claim Rejections – Enablement

Claims 10-18 and 20-24 have been rejected under 35 U.S.C. § 112, first paragraph. This rejection is respectfully traversed. Reconsideration and withdrawal thereof are requested.

The Examiner basically urges that the claims are only enabled for cells of *Crithmum maritimum*, since these are the only cells described in the working examples. Applicants submit that the Examiner's rejection is not proper, and the Examiner has failed to provide a sufficient basis for the enablement rejection.

In order to be considered enabling, the specification must teach one skilled in the art how to make and use the full scope of the claimed invention without “undue experimentation”. *In re Wright*, 27 USPQ2d 1510, 1513; Citing *In re Vaeck*, 20 USPQ 1438, 1444 (Fed. Cir. 1991). However, it is also well settled that “nothing more than objective enablement is required, and

therefore it is irrelevant whether this teaching is provided through broad terminology or illustrated examples.” *In re Wright*, 27 USPQ at 1513; Citing *In re Marzocchi*, 169 USPQ 367, 369 (CCPA 1971). In the present application, the Applicants describe that halophytic plants have developed defenses against salinity and that dermatological extracts prepared from dedifferentiated cells of these particular plant species possess the property of depigmenting/lightening of the skin, and show similar activity with regard to inhibition of melanin. In addition, Applicants describe a number of species of halophytic plants useful in the invention. (See specification at page 6, lines 2-23).

While it is true that the working examples in the application only relate to *Crithmum maritimum*, the Examiner’s singular focus on the working examples is misplaced and improperly fails to consider the other teachings in the application that provide those skilled in the art with a disclosure sufficient to enable one skilled in the art to practice the full scope of Applicants’ invention.

Examples 1, 2 and 4 of the application teach an *in vitro* method of culturing dedifferentiated cells from a plant tissue (see page 8), a method of preparing a lyophilisate from cultivated cells (see page 10), and an experimental protocol for assessing the depigmenting effect of a cosmetic preparation containing a lyophilisate of differentiated cells (see page 13). Following these teachings, one skilled in the art would be able to practice the invention with other species of halophytic plant cells, including the other species described at page 6 of the specification, without undue experimentation.

It is well established that a rejection of claims for lack of enablement requires the USPTO to first set forth “a reasonable explanation as to why it believes the scope of protection provided by that claim is not adequately enabled by the description of the invention provided in the specification”. *In re Wright*, 27 USPQ2d at 1513, Citing *Marzocchi*, 169 USPQ at 369-70. In the present case, the Examiner has not at all explained why one skilled in the art would not be able to practice the full scope of Applicants’ claimed invention. Instead, the Examiner merely makes conclusory statements that the scope of the claims “is clearly beyond the scope of the instantly

claimed/disclosed invention” or that “it would take undue experimentation without a reasonable expectation of success for one of skill in the art to make and/or use the instantly claimed composition”. But conclusory statements of this type are not a reasonable explanation for objecting to Applicants’ enabling disclosure.

Accordingly, reconsideration and withdrawal of the rejection are requested.

### 7.2. Claim Rejections – Indefiniteness

The Examiner has objected to the claims for the use of the phrase “halophile plant cells”. As suggested by the Examiner, this phrase has been replaced with the term “halophytic plant cells” in claims 10 and 20, thereby obviating the rejection.

## **8. Claim Rejections – 35 U.S.C. § 103**

### 8.1 Claim Rejections – *Majmudar* In View of *Ennamany*

Claims 10-18 and 20-24 have been rejected under 35 U.S.C. § 103(a) over *Majmudar* (U.S. 2005/0123499) in view of *Ennamany* (WO 03/077881). This rejection is respectfully traversed. Reconsideration and withdrawal thereof are requested.

*Majmudar* discloses a composition comprising at least one, two or three of algae extracts, sea fennel, or *Codium tomentosum* extract. The compositions of *Majmudar* are taught as being useful to treat aged or damaged skin. First of all, *Majmudar* does not in any way teach or suggest compositions having a depigmenting effect on the epidermis. Rather, *Majmudar* teaches compositions useful to renew the damaged layers of skin, such as the stratum corneum, leading to an improved appearance and higher clarity (see paragraphs [0007] and [0013] of *Majmudar*). Depigmenting effects, as in the present invention on the other hand, result from the inhibition of melamine synthesis in the reconstructed epidermis by blocking tyrosinase activity which leads to depigmentation of the skin (see the present application at, for example, page 14). Thus, the purpose and effects of the compositions of *Majmudar* are clearly different from those of the

present invention. That is, while the compositions of *Majmudar* are used for the treatment of damaged skin of particularly aged persons, the composition of the present invention is useful for lightening black or asian skins, for example, or otherwise producing a depigmenting effect on the skin of any age. This depigmenting effect is not at all suggested in *Majmudar*.

In addition, *Majmudar* does not in any way teach or suggest the use of dedifferentiated plant cells, or a lyophilisate of dedifferentiated plant cells. Recognizing this deficiency in the reference, the Examiner urges a combination of *Majmudar* with *Ennamany*. But Applicants suggest that there is no basis for the Examiner's suggested combination of references, and even the alleged combination would not teach or suggest the present invention.

First of all, *Ennamany* is directed to cosmetic compositions containing at least one phytoalexin. The dedifferentiated plant cells of *Ennamany* are specifically cultured to synthesize at least one phytoalexin. These compounds are effectively antibiotics which are synthesized as a defense mechanism of the living cells in response to exposure to pathogens. This is far different from the present invention wherein the dedifferentiated plant cells are from halophytic plant cells capable of tolerating high salinity. Because of these significant differences, Applicants submit that one skilled in the art would not even be lead to combine the teachings of *Majmudar* with those of *Ennamany*.

The lack of motivation to combine the references is further emphasized when one recognizes that the teachings of *Ennamany* are limited to the plant genera described at, for example, paragraph [0112]. None of these plants are halophytic plants. As such, one skilled in the art would not be lead to combine the teachings of *Ennamany et al.* with those of *Majmudar* when the two references are direct to the use of vastly different types of plants.

Finally, even if one were to combine the teachings of *Ennamany* with those of *Majmudar*, the resulting composition would be one containing the dedifferentiated plant cells from the plants described by *Ennamany et al.*, but that combination is not the same as the composition of the

present invention which is direct to compositions containing at least one lyophilisate of dedifferentiated halophytic plant cells.

Accordingly, Applicants submit that the Examiner's combination of references does not teach or suggest the present invention so that the rejection should be withdrawn.

### 8.2 Claim Rejections – Mikimoto in view of Ennamany

Claims 10-18 and 21-24 have been rejected under 35 U.S.C. § 103(a) over *Mikimoto* (JP 2003-160461) in view of *Ennamany*. This rejection is respectfully traversed. Reconsideration and withdrawal thereof are requested.

Applicants submit that this combination of references fails to teach the present invention for reasons essentially the same as discussed above. That is, while *Mikimoto* describes a cosmetic composition comprising *Tamarix chinensis* or its solvent extract, the reference does not in any way teach or suggest the use of dedifferentiated plant cells, nor the use of a lyophilisate of dedifferentiated plant cells. Recognizing this deficiency, the Examiner urges a combination of *Mikimoto* with *Ennamany*.

But as discussed above, the teachings of *Ennamany* are directed to a different kind of topical composition, and specifically are directed to compositions containing at least one phytoalexin. The types of plants and compositions described in *Ennamany* are far different from those described in *Mikimoto*, such that one skilled in the art would not be lead to combine the teachings of the two references.

In addition, even if one skilled in the art were to combine *Mikimoto* with *Ennamany*, the resulting composition would contain dedifferentiated plant cells as taught by *Ennamany* which are far different from the halophylic plant cells in the composition in the present invention.

In view of the above, reconsideration and withdrawal of the rejections and early allowance of all the claims are requested.

Pursuant to 37 C.F.R. §§ 1.17 and 1.136(a), Applicant(s) respectfully petition(s) for a two (2) month extension of time for filing a reply in connection with the present application, and the required fee of \$460.00 is attached hereto.

If the Examiner has any questions concerning this application, the Examiner is requested to contact Leonard R. Svensson, Reg. No. 30,330 at the telephone number of (858) 792-8855. Facsimile communications may be sent to the undersigned at the facsimile number of (858) 792-3785.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37 C.F.R. § 1.16 or under 37 C.F.R. § 1.17; particularly, extension of time fees.

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Respectfully submitted,

By 

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Attachments